UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

IN RE:	:	MDL DOCKET NO. 1724
VIAGRA PRODUCTS LIABILITY LITIGATION	:	Judge Paul A. Magnuson
	:	
This Document Relates To: ***Martin v. Pfizer Inc.*, 0:06-cv-01064-PAM** ***Stanley v. Pfizer Inc.*, 0:06-cv-01065-PAM**	:	

DEFENDANT PFIZER INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO EXCLUDE THE TESTIMONY OF CHERYL BLUME, PhD

Dated: New York, New York
May 28, 2009

KAYE SCHOLER LLP
Steve Glickstein
Lori B. Leskin
Mark Spatz
425 Park Avenue
New York, NY 10022
212-836-8000

OPPENHEIMER WOLFF & DONNELLY
David P. Graham
3300 Plaza VII
45 S. Seventh Street
Minneapolis, MN 55402
612-607-7000

Counsel for Pfizer Inc.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

Page(s)

RULES

Page(s)

Defendant Pfizer Inc ("Pfizer") submits this memorandum of law in support of its motion to exclude the proposed expert testimony of Dr. Cheryl Blume.

PRELIMINARY STATEMENT

Cheryl Blume, Ph.D., is plaintiffs' proposed FDA regulatory expert. Plaintiffs have asked her to "address the scientific and regulatory actions taken by Pfizer in the development, post-launch evaluations, labeling and marketing of Viagra (sildenafil), particularly as they relate to Non-Arteritic Ischemic Optic Neuropathy (NAION)."[1]

Dr. Blume's primary opinion is that as early as 2000, Pfizer's awareness of a small number of reports of NAION – out of the millions of men who used Viagra – should have prompted the Company to change the Viagra label to include a statement about NAION and also to conduct an epidemiologic study to investigate the potential relationship.[2] The United States Food and Drug Administration ("FDA") has established guidelines for assessing and reacting to adverse event reports. Dr. Blume's opinions are not grounded in these guidelines or, for that matter, any FDA regulations. In fact, as discussed below, her opinions directly contradict FDA guidelines. An FDA regulatory expert must – by definition – base her opinions on FDA regulations. Without "any reference to FDA requirements" and "any testimony that [Pfizer's] actions violated FDA regulations or any other defined standard," Dr. Blume's regulatory opinions are simply

[1] Expert Report of Dr. Cheryl Blume ("Blume Rep.") at 3. The Blume Rep. is attached to the Affirmation of Lori B. Leskin ("Leskin Aff.") at Ex. 16.

[2] Deposition Transcript of Dr. Blume ("Blume Dep.") at 144–45 (Leskin Aff. Ex. 30).

personal views, and therefore inadmissible. *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 880 (E.D. Ark. 2008) (excluding regulatory expert's testimony that was not based on FDA guidelines or requirements). *See also In re Diet Drugs Prods. Liab. Litig.*, 2001 WL 454586, *17–18 (E.D. Pa. Feb. 1, 2001) (Leskin Aff. Ex. 98) (excluding regulatory expert's opinion because "[i]t does not appear to be based on an interpretation of FDA regulations or [his] experience in applying those regulations"). *Accord In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 543 (S.D.N.Y. 2004) (excluding experts' testimony on pharmaceutical company's breach of "ethical" duties because it was not grounded in any accepted standards; rather, "their opinions concerning purported ethical standards [were] based on their personal, subjective views"). *See* Points I and II below.

Dr. Blume also intends to testify about several other matters that are beyond her expertise, not the proper subject of expert testimony, and/or irrelevant.

First, Dr. Blume intends to testify about topics relating to the motive, intent and state of mind of Pfizer, patients and physicians. Such testimony is beyond the expertise of any expert. Case law prohibits speculation by any expert about someone else's thoughts, and certainly a regulatory expert is unqualified to do so. *See In re Baycol Prods. Liab. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) ("[E]xpert testimony to the extent that [it] speculates as to Bayer's motive, intent or state of mind, or speculates as to motives of the FDA or what other drug companies would do is excluded."); *Rezulin*, 309 F. Supp. 2d at 546 (excluding expert opinions "on the intent, motives, or states of

mind of corporations, regulatory agencies and others" because they "have no basis in any relevant body of knowledge or expertise"). *See* Point III below.

Second, Dr. Blume intends to testify about foreign countries' regulation of Viagra to establish that certain foreign labels include "more significant contraindications" regarding NAION than the current U.S. label.[3] Dr. Blume admits that she is not an expert in foreign regulatory matters[4] – an admission which, by itself, compels exclusion of the testimony. Moreover, as numerous courts have held, in a product liability litigation involving events that occurred only in the United States, the foreign regulation of a drug is irrelevant and its introduction would cause substantial jury confusion. *See, e.g.*, *Baycol*, 532 F. Supp. 2d at 1054 (excluding evidence of foreign regulatory actions because it was irrelevant and would likely cause jury confusion); *In re Seroquel Prods. Liab. Litig.*, 601 F. Supp. 2d 1313, 1318 (M.D. Fla. 2009) (excluding evidence of foreign regulatory actions because the "probative value is greatly overmatched by the jury confusion, waste of time, and unfair prejudice that would result if the Court were to allow Plaintiffs to introduce this evidence during their main case"). *See* Point IV below.

Third, Dr. Blume intends to testify about regulatory actions relating to three Viagra advertisements. But these advertisements are irrelevant to this litigation because two of them post-date plaintiffs' last use of Viagra and there is no evidence that the third was seen or relied upon by plaintiffs or their prescribing physicians. *See Daubert v.*

[3] Blume Rep. 28; Blume Dep. 285–86.

[4] Blume Dep. 286.

Merrell Dow Pharm., Inc., 509 U.S. 579, 591 (1993) ("'Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful'") (citations omitted). *See* Point V below.

Finally, Dr. Blume intends to testify about facts relating to Viagra's regulatory history. Such non-opinion testimony is "merely a 'narrative of the case which a juror is equally capable of constructing,'" and is therefore inadmissible. *Rezulin*, 309 F. Supp. 2d at 551 (excluding expert's "history of Rezulin," which recited selective regulatory events relating to the drug). To the extent Dr. Blume seeks to put her "spin" on the regulatory facts, that also is inadmissible. *See Prempro*, 554 F. Supp. 2d at 887 (excluding expert's testimony where expert simply summarized a document "with a tilt favoring a litigant without more"). *See* Point VI below.

In addition to her improper expert opinions, Dr. Blume has failed to disclose many of the bases for her opinions in violation of Fed. R. Civ. P. 26(a)(2), despite repeated requests for such information. Fed. R. Civ. P. 37(c)(1) requires that Dr. Blume's testimony be excluded to the extent it is premised on materials that have not been disclosed. *See* Point VII below.

LEGAL STANDARD

"Opinion given through the mouth of an expert does not necessarily make it expert opinion." *Prempro*, 554 F. Supp. 2d at 887. Rather, Fed. R. Evid. 702 imposes specific limitations on the admissibility of expert testimony. Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or

> education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The hallmark of admissible expert testimony under Rule 702 is that it concerns "scientific, technical or other specialized *knowledge*." Fed. R. Evid. 702 (emphasis added). Testimony consisting merely of personal opinion is not "scientific, technical, or other specialized knowledge," because "the word 'knowledge' connotes more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 589–90. *Accord Rezulin*, 309 F. Supp. 2d at 541 ("[T]he requirement of 'knowledge' guards against the admission of subjective or speculative opinions."). As the *Baycol* MDL Court stated, "expert testimony that is merely speculation or pure conjecture . . . must be excluded as not based on any reliable methodology or scientific principle." 532 F. Supp. 2d at 1053.

In accord with the requirement that expert testimony be based on "more than subjective belief or unsupported speculation," the Supreme Court in *Daubert* held that "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." 509 U.S. at 589. Six years after *Daubert*, in *Kumho Tire Co. v. Carmichael*, the Supreme Court extended the gatekeeping function of federal courts "not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." 526 U.S. 137, 141 (1999). *Kumho* succinctly framed the objective of *Daubert*: "to make certain that an expert, whether basing testimony upon professional studies or personal experience, *employs in*

the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152 (emphasis added). *Accord In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d 1071, 1077 (D. Minn. 2008) (quoting *Kumho Tire*).

Necessarily, an FDA regulatory expert employing "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field" must link that opinion to FDA regulations. Dr. Blume has not done so. Regulatory opinions that are "missing [] any reference to FDA requirements" and are "devoid of any testimony that [a company's] actions violated FDA regulations or any other defined standard" are inadmissible. *Prempro*, 554 F. Supp. 2d at 880. *Accord Diet Drugs*, 2001 WL 454586, at *17–18 (excluding regulatory expert's opinion that was not based on FDA regulations); *Rezulin*, 309 F. Supp. 2d at 543 (excluding ethics opinions that were not grounded in any accepted standards).

ARGUMENT

I. DR. BLUME'S TESTIMONY THAT THE VIAGRA LABEL SHOULD HAVE REFERRED TO NAION IN THE YEAR 2000 IS NOT BASED ON FDA GUIDELINES AND IS IN FACT CONTRARY TO FDA GUIDELINES

Plaintiffs hired Dr. Blume to assess Pfizer's pharmacovigilance efforts as they related to NAION.[5] FDA defines pharmacovigilance as "all scientific and data gathering activities relating to the detection, assessment, and understanding of adverse

[5] Blume Rep. 3; Blume Dep. 15–16.

events."[6] To that extent, Dr. Blume opines that as of the year 2000, the existence of a small number of NAION reports constituted a safety signal that should have prompted Pfizer to add a warning about NAION to the Viagra label and to initiate an epidemiology study. As discussed above, Dr. Blume's opinions relating to Pfizer's pharmacovigilance efforts must be grounded in FDA regulations or guidelines.

FDA has promulgated the "Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment ("Guidance for Industry"), in part, to provide "guidance to industry on good pharmacovigilance practices."[7] FDA's Guidance for Industry provides a standard framework for evaluating adverse event reports and potential safety signals. As shown below, in formulating her opinion, Dr. Blume failed to apply such standard pharmacovigilance procedures, or indeed any FDA regulations. In fact, *contrary to FDA guidelines*,

- Dr. Blume applied the wrong definition of a safety signal (and, in fact, rejected the FDA's definition);
- She did not review the adverse event reports;
- She did not put the reports into context by considering the millions of men who take Viagra and the background rate of NAION;
- She compared the number of Viagra reports in the FDA's adverse event reports database to the number of reports for drugs in *different pharmaceutical classes*; and

[6] FDA, Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment 4 (Mar. 2005) ("Guidance for Industry") (Leskin Aff. Ex. 71).

[7] Guidance for Industry, at 1.

- She relied on case reports and other literature that are not related to NAION.

In addition, Dr. Blume reached her conclusions before she had the adverse event data that she testified "corroborated" her opinion.[8] Further, and most critically, Dr. Blume cannot cite any authority holding that the existence of a given number of adverse event reports requires a label change or an epidemiology study.

Each of these deficiencies on its own demonstrates severe methodological flaws, which render Dr. Blume's opinion inadmissible. Taken together, however, it is plain that Dr. Blume's opinion is "pure conjecture" that "must be excluded as not based on any reliable methodology or scientific principle." *Baycol*, 532 F. Supp. 2d at 1053.

A. Dr. Blume's Definition of a Safety Signal Contradicts the FDA's Definition

The primary purpose of pharmacovigilance is the "identification and evaluation of safety signals."[9] Thus, the linchpin of Dr. Blume's opinion that Pfizer should have changed Viagra's label in 2000 is her assertion that there was a safety signal.[10] FDA defines a safety signal as "a concern about an excess of adverse events *compared to what would be expected to be associated with a product's use*."[11] In

[8] Blume Dep. 157.

[9] Guidance for Industry, at 4.

[10] Blume Dep. 132–33.

[11] Guidance for Industry, at 4 (emphasis added).

reaching her conclusion that there was a safety signal in 2000, Dr. Blume did not employ this standard definition.

Dr. Blume described a safety signal as "any issue that you observe with your data that makes you think differently."[12] In elaborating upon this definition, Dr. Blume testified that she "generally do[es] not qualify whether something is a signal or not based on what I would anticipate to see in a given population, simply because we are instructed to not do that."[13] When asked to cite a source for her definition of a signal, Dr. Blume asserted, in conclusory fashion – without citing any source – that it was "FDA's definition of a signal."[14]

On its face, however, Dr. Blume's understanding of a safety signal is at odds with FDA's definition. Indeed, at her deposition, Dr. Blume did not even recognize a word-for-word quote of FDA's definition of safety signal:

> Q. . . . [W]ould you agree with me that *a safety signal is a concern about an excess of adverse events compared to what would be expected to be associated with a product's use*?
>
> A. Well, my understanding of a safety signal is any issue that you observe with your data that makes you think differently. And it can include a new event or some change in the frequency or magnitude of a previous event. *I generally do not qualify whether something is a signal or not based on what I would anticipate to see in a given population, simply because we are instructed not to do that*.[15]

---

[12] Blume Dep. 85.

[13] *Id.* at 135–36.

[14] *Id.* at 138.

[15] *Id.* at 85 (emphasis added).

By specifying that the adverse events must be "compared to what would be expected to be associated with a product's use," FDA's definition of a safety signal demands that the adverse events be put into context – which is precisely what Dr. Blume testified the FDA instructs industry *not* to do.[16]

In *Diet Drugs*, the MDL Court excluded testimony of the plaintiffs' regulatory expert that contradicted FDA regulations. Plaintiffs' expert offered an opinion that "consumers should be warned about drugs directly although FDA regulations prohibit this." *Diet Drugs*, 2001 WL 454586, at *17. In excluding the testimony, the Court held that it was not "based on an interpretation of FDA regulations or [the expert's] experience in applying those regulations." *Id.* at *18. Moreover, the Court noted that such

> testimony runs contrary to controlling law as reflected in [FDA] regulations and the learned intermediary doctrine, which mandate that accurate warnings be directed to the physician rather than to the patient. Thus, it is not an "expert" opinion, but rather a personal opinion about what standards [plaintiffs' expert] believes should apply to pharmaceutical company conduct.

Id. Similarly, Dr. Blume's definition of a safety signal is simply her own personal definition of the term, which is contrary to FDA's definition. By employing a definition of a safety signal that is inconsistent with FDA's definition, and for which Dr. Blume cannot cite any authority, the regulatory opinions that flow from that definition are inherently unreliable and, therefore, inadmissible.

[16] *Id.* at 57–58, 85, 138.

B. Dr. Blume's Consideration of the Number of NAION Reports, Without Even Reading the Reports Themselves to Evaluate Their Quality, Contradicts FDA Guidelines

In assessing whether there is a safety signal, "FDA suggests that case-level review occur *before* other investigations or analyses."[17] Contrary to this FDA guideline, Dr. Blume did not review any of the reports that form the basis for her opinion that there was a safety signal. Rather, at the time she drafted her report, Dr. Blume concluded that there was a safety signal because of the mere existence of some unspecified number of reports. At her deposition, by which time plaintiffs' counsel had told her that there were 12 reports of ischemic optic neuropathy (the general category of ophthalmologic conditions in which NAION events would have been categorized) in the FDA's adverse event reports database ("AERs database") by the end of 2000, she testified that those 12 reports constituted a signal.[18] Dr. Blume admitted that she made no effort to assess the quality of the reports:

Q. Did you look at the adverse events that were reported in 2000?

A. No. I know that they are serious suspect events.

---

[17] Guidance for Industry, at 6 (emphasis added). *Accord* Baum, C., et al., *The Spontaneous Reporting System in the United States*, *in* PHARMACOEPIDEMIOLOGY 125, 134 (B. Strom ed., 2d ed. 1994) (for all potential significant reports, FDA "evaluates the adequacy of the information on the report, the temporal association of the drug and the event, possible confounding factors such as patient disease or concomitant drug therapy, and dechallenge rechallenge information") ("Baum, *The Spontaneous Reporting System in the United States*") (Leskin Aff. Ex. 72).

[18] Blume Dep. 157, 136–37. As discussed in Part I.E below, the fact that Dr. Blume did not receive the "corroborat[ing]" evidence for her opinion until after she signed her report renders her opinion inadmissible.

Q. Did you look at the –

A. No.

Q. – MedWatch forms?

A. I did not look at the MedWatch forms.[19]

Dr. Blume cannot simply rely on the number of reports to determine that there was a safety signal because, under FDA guidelines, "[a]ccumulated reports cannot be used to calculate incidence (occurrence rates) or to estimate drug risk."[20] Rather, FDA emphasizes that "[t]he quality of the reports is critical for appropriate evaluation of the relationship between the product and adverse events."[21] Accordingly, "[a]s part of the case-level review, FDA suggests that sponsors *evaluate individual case reports for clinical content and completeness*, and follow up with reporters, as necessary."[22] In the context of NAION, such a review is critical because the risk factors for erectile

[19] Blume Dep. 150.

[20] FDA Office of Post-Marketing Drug Risk Assessment, "README.DOC" File for Quarterly Data Extract from the ADVERSE EVENT REPORTING SYSTEM 2 (Mar. 8, 2006) ("Mar. 8, 2006 Readme.doc") (Leskin Aff. Ex. 73). *Accord* FDA Office of Post-Marketing Drug Risk Assessment, "README.TXT" File for Quarterly Data Extract from the ADVERSE EVENT REPORTING SYSTEM 2 (June 25, 1999) ("June 25, 1999 Readme.txt") (same) (Leskin Aff. Ex. 74); *see also Baycol*, 532 F. Supp. 2d at 1039 (citing FDA Office of Post-Marketing Drug Risk Assessment, Adverse Event Reporting System (AERS): Brief Description with Caveats of System" 2 (Oct. 18, 1999)).

[21] Guidance for Industry, at 4. *Accord* Goldman, S.A., *Limitations and Strength of Spontaneous Reports Data*, 20C CLINICAL THERAPEUTICS 40, 42 (Supplement C 1998) ("The ability to assess, analyze, and act on safety issues based on spontaneous reporting is dependent on the quality of information submitted by health professionals in their reports.") (Leskin Aff. Ex. 75).

[22] Guidance for Industry, at 6 (emphasis added).

dysfunction and NAION overlap, making it impossible to rule out coincidence as a potential cause of NAION in cases where the person took Viagra.[23]

In *Diet Drugs*, the MDL Court considered testimony similar to Dr. Blume's. There, the Court excluded an expert's "opinion that 100 adverse event reports [in a single year] . . . should have triggered more warnings, evaluation and testing" because it was "based on his own personal opinion rather than any particular methodology." *Diet Drugs*, 2001 WL 454586, at *16. Accordingly, Dr. Blume's testimony should be excluded because, contrary to FDA regulations, she considered only the number of reports without actually looking at and analyzing them.

C. Dr. Blume's Failure to Consider the Small Number of Reports of NAION Among Viagra Users in the Context of the Background Rate or the Millions of Men Who Used Viagra Contradicts FDA Guidelines

According to FDA guidelines, "[i]f a sponsor determines that a concern about an excess of adverse events or safety signal warrants further investigation and analysis, it is important to put the signal into context."[24] This requires both a "background rate . . . for the event being evaluated" and an understanding that there are

[23] *See* FDA Statement, FDA Updates Labeling for Viagra, Cialis, and Levitra for Rare Post-Marketing Reports of Eye Problems (July 8, 2005) (Leskin Aff. Ex. 3). *Accord* Testimony of Plaintiffs' Experts: Deposition Transcript of Dr. Williams ("Williams Dep.) at 118–21, 134 (Leskin Aff. Ex. 36); Deposition Transcript of Dr. Lee ("Lee Dep.") at 108–09, 137–41 (Leskin Aff. Ex. 31); Deposition Transcript of Dr. Sher ("Dr. Sher Dep.") at 191–94, 201–03 (Leskin Aff. Ex. 35).

[24] Guidance for Industry, at 10.

"many other factors [that may] affect the reporting of product-related adverse events," including "publicity" and "newness of product to the market."[25]

Contrary to these guidelines, Dr. Blume did not assess the context in which the NAION reports were generated by considering the background rate of NAION or the millions of men who take Viagra. First, as she did with her definition of a "safety signal," Dr. Blume asserted, in direct contradiction of FDA guidelines, that one is not supposed to consider the background rate in assessing a signal:

> Q. . . . And do you know what the background rate is for NAION in men with erectile dysfunction?
>
> A. No. Remember, regulatory opinions, we are directed by FDA that background incidences do not impact the way we handle labeling or information relating to diseases. In fact, we are specifically directed not to consider background incidences. We are looking at an adverse event and deciding what to do with it from a regulatory perspective.[26]

In addition, Dr. Blume failed to consider the reports in the context of the millions of men who took Viagra. Dr. Blume understood that about 30 million men had taken Viagra since it was first marketed in 1998.[27] And by the end of 2000, at which point Dr. Blume notes the 12 reports in FDA's AERs database, "Sildenafil had been

---

[25] *Id.* at 11, 12. *Accord* Baum, *The Spontaneous Reporting System in the United States*, at 132 (several factors affect reporting rates including "[t]he length of time a drug has been marketed," "publicity in the mass media," and "an article in the professional literature").

[26] Blume Dep. 57–58.

[27] *Id.* at 142.

prescribed to more than 10 million patients worldwide."[28] Certainly, 12 reports among 10 million users is different from 12 reports in 10,000 users or even one million users. Indeed, 12 reports are far fewer than what one would have expected in the general population. As Dr. Blume cited in her report, the background rate of NAION has been estimated to be between 2.3 and 10.3 cases per 100,000 individuals.[29] Therefore, assuming these numbers are correct, by the end of 2000, one might have expected between 230 and 1,030 NAION events among the 10 million men who used Viagra – far greater than the 12 reports on which Dr. Blume relies.

As discussed above, FDA defines a safety signal as "a concern about an excess of adverse events *compared to what would be expected to be associated with a product's use*."[30] Thus, by definition, FDA guidelines require that to determine whether a safety signal exists, a company must determine whether there is an "excess" number of adverse events "compared to what would be expected" in the patient population using the drug. Dr. Blume did not do this, and her testimony is therefore inadmissible.

D. Dr. Blume's Comparison of the Number of Reports for Viagra to the Number of Reports for Dissimilar Drugs Contradicts FDA Regulations

Instead of comparing the number of adverse event reports to the expected background rate among the millions of Viagra users, Dr. Blume uses "data mining" to

---

[28] R. Sadovsky et al., *Three Year Update of Sildenafil Citrate (Viagra) Efficacy and Safety*, 55 INT'L J. CLIN. PRACT. 1, 1 (Mar. 2001) (Leskin Aff. Ex. 76).

[29] Blume Rep. 15.

[30] Guidance for Industry, at 4 (emphasis added).

compare the number of reports for Viagra to the number of reports for a handful of other drugs that are not in the same pharmaceutical class as Viagra.[31] FDA defines "data mining" as "systematic examination of the reported adverse events by using statistical or mathematical tools."[32] Specifically, Dr. Blume looked at the number of reports of ischemic optic neuropathy ("ION") for four drugs – Amiodarone, Interferon, Viagra and Vioxx – from 1999 through 2004.[33] The analysis demonstrated that by 2000 Viagra had the most cumulative reports – a total of 12 – of ION among the four drugs.[34] Dr. Blume's reliance on such an analysis does not comport with FDA guidelines.

First, FDA cautions that "[c]omparisons between drugs *cannot* be made from [AER] data."[35] Indeed, "AER data and analyses have not been a generally accepted method by which to compare drugs." *Baycol*, 532 F. Supp. 2d at 1051 (excluding expert's opinion that Baycol was more dangerous than other statins because it was based primarily on AER data). Moreover, Dr. Blume's citation to FDA's prior use of such a comparison is misplaced. As support for her comparison of the number of Viagra reports to the number of reports regarding other drugs, Dr. Blume testified that FDA removed Baycol – a cholesterol lowering drug that is part of the class of drugs known as statins –

---

[31] *See* Blume Dep. Ex. 10 (Leskin Aff. Ex. 77); *see also* Guidance for Industry, at 8.

[32] Guidance for Industry, at 8.

[33] Blume Dep. Ex. 10.

[34] *Id.*

[35] Mar. 8, 2006 Readme.doc, at 2 (emphasis added). *Accord Baycol*, 532 F. Supp. 2d at 1039 (same); June 25, 1999 Readme.txt, at 2 (same).

from the market after "compar[ing] Baycol's adverse events relating to rhabdomyolysis with those of other statins."[36] Unlike Dr. Blume, however, FDA compared the adverse events associated with Baycol to those of drugs in the *same therapeutic class*. In contrast, Dr. Blume compared the reports of ION in Viagra patients to reports of ION in patients taking drugs with entirely different therapeutic purposes.[37]

Further, according to FDA, data mining "is not a required part of signal identification or evaluation" but, if it is employed, it involves substantially more than Dr. Blume's comparison of the number of adverse event reports for Viagra to other drugs:

> If data mining results are submitted to FDA, they should be presented in the larger appropriate clinical epidemiological context. This should include (1) a description of the database used, (2) a description of the data mining tool used (e.g., statistical algorithm, and the drugs, events and stratifications selected for the analyses) or an appropriate reference, and (3) a careful assessment of individual case reports and any other relevant safety information related to the particular drug-event combination of interest (e.g., results from preclinical, clinical, pharmacoepidemiologic, or other available studies).[38]

Dr. Blume has done no such work, and her opinion is therefore inadmissible.

---

[36] Blume Dep. 196.

[37] Amiodarone is an antiarrhythmia drug. *See* Amiodarone HCL Label (Leskin Aff. Ex. 78). Interferon is used to manage diseases involving the immune system. *See* Interferon alpha-2a Label (Leskin Aff. Ex. 79). Vioxx was used to treat arthritis and other conditions causing chronic or acute pain. *See* Vioxx Label (Leskin Aff. Ex. 80).

[38] Guidance for Industry, at 9–10.

E. Dr. Blume's Formulation of Her Opinion Before Obtaining the Necessary Data Violates *Daubert*

Even if Dr. Blume's pharmacovigilance assessment did not contradict FDA guidelines, in violation of good scientific methodology, she reached her conclusion that there was a safety signal *before* she had data to support her opinion. In her report, Dr. Blume did not cite the number of reports for Viagra and NAION. After writing her report, plaintiffs' attorney, Keith Altman, provided Dr. Blume with the "corroborat[ing]" data for her opinions – the chart comparing the number of reports of ION for Viagra to the number of reports for three dissimilar drugs that showed that, by the end of 2000, there were 12 reports for Viagra:

> Q. When did you receive this chart from Mr. Atlman?
>
> A. Oh, gee. I don't know. I don't know. I'll have to check. I don't know when I got it.
>
> Q. Was it before or after you signed your report in this case?
>
> A. I think it was after.
>
> Q. So that information that you have in your hand did not form the basis for the opinions as expressed in your expert report dated December 1st, 2008; is that fair to say?
>
> A. No, probably not. It corroborates it, but no. I had the opinion long before I saw any of the – yeah, I had the opinion earlier. [39]

[39] Blume Dep. 157. Not only did Dr. Blume not have the AER analysis that corroborated her opinions until after she signed her report, she did not conduct the analysis herself. Rather, plaintiffs' counsel, Keith Altman, did the analysis. In addition, she did nothing to verify the information in the analysis "[b]ecause Mr. Altman has done this repeatedly for [her] for years." Blume Dep. 150–51. Indeed, she took the information from Mr. Altman at face value. Courts have held that an expert's heavy reliance on facts provided by a lawyer, without independent investigation, "in and of itself, renders the testimony

(continued...)

Courts applying *Daubert* have routinely held that "an expert may not reach his conclusion first and do the research later." *Rezulin*, 309 F. Supp. 2d at 550. In *Claar v. Burlington N.R.R. Co.*, 29 F.3d 499, 503 (9th Cir. 1994), the Court of Appeals affirmed the exclusion of expert testimony, holding that:

> [S]cientists whose conviction about the ultimate conclusion of their research is so firm that they are willing to aver under oath that it is correct prior to performing the necessary validating tests could properly be viewed by the district court as lacking the objectivity that is the hallmark of the scientific method.

As *Claar* explained: "Coming to a firm conclusion first and then doing research to support it is the antithesis of [the scientific] method." *Id.* at 502–03. *Accord Rezulin*, 309 F. Supp. 2d at 550 n.64 (same); *Castellow v. Chevron USA*, 97 F. Supp. 2d 780, 793 (S.D. Tex. 2000) (same); *Mitchell v. Gencorp. Inc.*, 165 F.3d 778, 783 (10th Cir. 1999) (same). Indeed, this "turns scientific analysis on its head." *Sorensen v. Shaklee Corp.*, 31 F.3d 638, 649 (8th Cir. 1994) (expert testimony excluded where, "[i]nstead of reasoning from known facts to reach a conclusion, the experts [] reasoned from an end result in order to hypothesize what needed to be known but what was not").

Dr. Blume's concession that she received the adverse event data after she signed her report is a textbook example of "[c]oming to a firm conclusion first and then doing research to support it." *Claar*, 29 F.3d at 502–03. Opinions that are not "supported by appropriate validation – *i.e.*, 'good grounds,' based on what is known" – are inadmissible. *Daubert*, 509 U.S. at 590. *Accord Glastetter v. Novartis Pharm. Corp.*,

---

inadmissible" under *Daubert*. *MTX Comms. Corp. v. LDDS/WorldCom, Inc.*, 132 F. Supp. 2d 289, 292–93 (S.D.N.Y. 2001).

252 F.3d 986, 988 (8th Cir. 2001) (quoting *Daubert*). Plainly, an expert report that is written before the expert had the corroborating evidence is neither "supported by appropriate validation" nor based on "good grounds." Dr. Blume's testimony should therefore be excluded.

F. Dr. Blume's Consideration of Evidence That Has No Connection to NAION Is Not Relevant and, Therefore, Not Reliable

In further support of her opinion that there was a signal as early as 2000, Dr. Blume also discusses the existence of case reports and certain other studies that have no connection with NAION. For example, in her report Dr. Blume cites 16 case reports involving conditions such as third-nerve palsy, retinitis pigmentosa, diabetic retinopathy, retinal detachment, and macular detachment, all which bear no relation to NAION.[40] Dr. Blume admitted that she does not even know what these conditions are or whether any of these conditions are related to NAION.[41] For example, with respect to third-nerve palsy, Dr. Blume testified as follows:

> Q. Do you know what third nerve palsy is?
>
> A. No.
>
> Q. Is it – do you have an opinion as to whether third nerve palsy is related to NAION?
>
> A. No.
>
> Q. Are you aware of any study demonstrating that third nerve palsy is related to NAION?

[40] Blume Rep. 16–17; Blume Dep. 171–72; 210–11; 249–50; 263–64.

[41] Blume Dep. 69–84.

A. No.[42]

The requirement in Fed. R. Evid. 702 "that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue' . . . goes primarily to relevance. 'Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.'" *Daubert*, 509 U.S. at 591 (citation omitted). *Accord Viagra*, 572 F. Supp. 2d at 1086 (quoting *Daubert*). Thus, the court must ensure that the proposed expert testimony is "relevant to the task at hand." *Daubert*, 509 U.S. at 597.

Messrs. Stanley and Martin allege that Viagra caused them to develop NAION. They did not experience any other ophthalmologic condition, let alone one that they attribute to their alleged ingestion of Viagra. Thus, Dr. Blume's reliance on case reports bearing no relationship to NAION is irrelevant.

Dr. Blume, who is not an ophthalmologist[43] and did not consult with any ophthalmologist in preparation of her report,[44] also asserts that there are "several lines of evidence [that] support the possibility of a drug-induced effect."[45] First, none of the evidence she cites addresses the potential relationship between Viagra and NAION. In

[42] *Id.* at 69.

[43] Blume Dep. 9.

[44] *Id.*

[45] Blume Rep. 18. Though she is not offering a causation opinion, Blume Dep. 52, Dr. Blume cites such evidence as support for her opinion that there was a safety signal in 2000.

fact, on its face, much of the literature does not relate either to Viagra or NAION, and Dr. Blume cannot connect this "evidence" to Viagra or NAION. For example, as evidence that "animal studies [] support the biologic plausibility of Viagra inducing NAION," she points to studies regarding the potential link between phosphodiesterase inhibitors and impaired retinal function (*i.e.*, retinal toxicity).[46] Four of the six studies she cites do not discuss Viagra; indeed, they were all published long before Viagra was on the market.[47] Further, none of the articles connect retinal toxicity to NAION, and at her deposition Dr. Blume could not identify the scientific literature upon which she relied to make this connection.[48]

An expert opinion "connected to existing data only by the *ipse dixit* of the expert" is inadmissible where "there is simply too great an analytical gap between the data and the opinion proffered." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

---

[46] Blume Rep. 18; Blume Dep. 263–77.

[47] *See* Hotta H, et al., *A Selective Camp Phosphodiesterase Inhibitor, Dilates Retinal Arterioles and Increases Retinal and Choroidal Blood Flow in Rats*, 344 EUR J PHARMACOL 49–52 (1998) (cited in Blume Rep. 18) (Leskin Aff. Ex. 81); Ulshafer RJ, et al., *Sensitivity of Photoreceptors to Elevated Levels of Cgmp in the Human Retina*, INVEST OPHTHALMOL VIS SCI 19(10):1236-41 (1980) (cited in Blume Rep. 18) (Leskin Aff. Ex. 82); LaVail MM & Sidman RL, *C57BL-6J Mice with Inherited Retinal Degeneration*, ARCH OPHTHALMOL 91(5):394-400 (1974) (cited in Blume Rep. 18) (Leskin Aff. Ex. 83); Farber DB & Lolley RN, *Enzymic Basis for Cyclic GMP Accumulation in Degenerative Photoreceptor Cells of Mouse Retina*, J CYCLIC NUCLEOTIDE RES 2(3):139-48 (1976) (cited in Blume Rep. 18) (Leskin Aff. Ex. 84).

[48] Blume Dep. 264–66, 271–72. As discussed in Part VII below, Dr. Blume should be precluded from offering any opinions relating to retinal toxicity because she has not provided the materials upon which she claims she relied in forming her opinion that retinal toxicity is in any way related to NAION.

Accord Viagra, 572 F. Supp. 2d at 1077 (quoting *Joiner*). Without any evidence linking the miscellaneous studies cited in her report with Viagra and/or NAION, Dr. Blume fails to connect the evidence with her opinions. Therefore, her reliance on such materials to establish that there was evidence of biological plausibility, and accordingly a safety signal requiring a label change, is inadmissible.[49]

In sum, FDA's pharmacovigilance guidelines provide a methodological framework for assessing the thousands of adverse event reports that a pharmaceutical company receives regarding a drug. In contrast, Dr. Blume's assessment of whether there was a safety signal with respect to NAION is based on little more than a tally of the adverse event reports for Viagra and NAION. As discussed above, a regulatory expert such as Dr. Blume is required to ground her testimony in FDA regulations. Dr. Blume did not do so. She cites no specific FDA authority – neither statutes, regulations nor guidance documents. She applies no peer-reviewed, published or generally accepted methodology. Instead, in purely conclusory terms, she states – solely by *ipse dixit* – that her views are consistent with FDA's. But as shown above, her methods and opinion are in direct conflict with FDA's recommended pharmacovigilance procedures. Her testimony is therefore inadmissible.

[49] In addition, to the extent that Dr. Blume relies on the McGwin study (2006) (Leskin Aff. Ex. 38) or the Margo & French study (2007) (Leskin Aff. Ex. 85) to argue that Pfizer should have changed its label, such arguments are misplaced because, by the time these two studies were published, Pfizer had amended the Viagra label to include a statement regarding NAION. *See* July 2005 Viagra Label (Leskin Aff. Ex. 2).

II. DR. BLUME'S OPINION THAT PFIZER SHOULD HAVE CONDUCTED AN EPIDEMIOLOGY STUDY OF VIAGRA AND NAION IN THE YEAR 2000 CONTRADICTS FDA GUIDELINES AND IS BASED ON SPECULATION

A. Dr. Blume's Opinion That Pfizer Should Have Conducted an Epidemiology Study in the Year 2000 Contradicts FDA Guidelines

Dr. Blume's opinion that Pfizer should have conducted an epidemiology study in 2000 is based on her view that there was a safety signal. As described above, Dr. Blume's methodology for determining that there was a safety signal is not grounded in FDA guidelines, and in fact contradicts FDA guidelines. Therefore, for the same reasons described above, her opinion that Pfizer should have conducted an epidemiology study is inadmissible.

Moreover, even if there were a safety signal in 2000, Dr. Blume does not cite any authority that the identification of a safety signal required a label change or an epidemiologic study. Contrary to Dr. Blume's personal opinion, FDA guidelines state that once a safety signal is identified, it should be "further assessed to determine whether it represents a potential risk and whether other action should be taken."[50] In other words, the identification of a safety signal does not demand an immediate label change; it only requires further investigation. While an epidemiology study is one way to investigate a safety signal, it is not the only method. Dr. Blume agrees that, to investigate a safety signal, a company can review its clinical database, review the existing literature, evaluate

[50] Guidelines for Industry, at 4.

whether there is a plausible biological mechanism, and consult with experts.[51] Similarly, "FDA recognizes that there are a variety of methods for investigating a safety signal" and "encourages sponsors to consider all methods to evaluate a particular safety signal."[52]

In *Prempro*, the court considered testimony similar to Dr. Blume's. In a case involving the hormone replacement drugs Prempro, Premarin and Provera, plaintiffs' regulatory expert testified that certain animal-study data should have prompted the defendant to conduct studies to determine the validity of that data. The court ruled that the testimony should have been excluded:

> Dr. Parisian testified only that Upjohn could have arrived at a different conclusion based on the data, and Upjohn could have done its own study to determine the validity. This is more argument than expert testimony. Furthermore, ***there was no testimony that Upjohn's decision not to conduct a study . . . violated any FDA regulations or breached any duty Upjohn might have to test***. Dr. Parisian's assessment of this document lacked any regulatory expertise, and I should have excluded the testimony.

Prempro, 554 F. Supp. 2d at 885 (emphasis added).

Dr. Blume's opinion that Pfizer should have initiated an epidemiology study after receiving a dozen NAION reports out of 10-million users is "missing [] any reference to FDA requirements" and is "devoid of any testimony that [Pfizer's] actions violated FDA regulations or any other defined standard." *Id.* at 880. Indeed, FDA advises that "it is *impossible* to delineate a universal set of criteria for the point at which a pharmacoepidemiologic study should be initiated, and the decision should be made on a

[51] Blume Dep. 92–95.

[52] Guidance for Industry, at 12.

case-by-case basis."[53] Such a purely personal opinion "does not qualify as expert testimony," and is therefore inadmissible. *See Baycol*, 532 F. Supp. 2d at 1067 (expert's opinion "criticizing Bayer for inadequately evaluating the potential toxicity of Baycol, and asserting that Bayer ignored warnings is legal argument that does not qualify as expert testimony under Rule 702").

B. Dr. Blume's Supposition That an Epidemiology Study of Viagra and NAION Would Have Shown a Causal Link Requiring a Label Change Is Irrelevant and Inadmissible Speculation

Dr. Blume's personal opinion that Pfizer should have conducted an epidemiology study in 2000 is inadmissible for the separate and independent reason that such testimony is irrelevant in the *Martin* and *Stanley* cases. That is because the results of a proposed study commenced in 2000 could not have affected Mr. Martin's or Mr. Stanley's decisions to take Viagra at the time of their alleged injuries.

Dr. Blume was asked how long it would take to complete her proposed study:

> Q. How long would a study like that take?
>
> A. All depends on how much effort they put into the study, how many ophthalmologic sites they were willing to open.
>
> Q. What's a range?
>
> A. A couple years. A couple years. Maybe longer. We don't know because they didn't do it. But I would imagine a couple years.[54]

[53] Guidelines for Industry, at 13 (emphasis added).

[54] Blume Dep. 146.

Messrs. Stanley and Martin developed NAION in 2000 and 2002, respectively. Because Dr. Blume testified that the epidemiology study should have been commenced in 2000, and because her proposed study would have taken "[a] couple years," "[m]aybe longer" to complete, it would not have been finished in time to change anything with respect to Messrs. Stanley and Martin.

In addition, although Dr. Blume contends that an epidemiology study would have shown a positive relationship between Viagra and NAION, she admitted that this is just an "assum[ption]" on her part.[55] Indeed, if the results of a study could be determined in advance, there would be no need to conduct it. Therefore, Dr. Blume is merely speculating when she states that if "a study had been initiated . . . it is likely the product labeling would contain more stringent language regarding NAION."[56]

As shown above, an expert's opinion must consist of more than speculation. *Daubert*, 509 U.S. at 590. Because Dr. Blume has no way of knowing what the results of her proposed epidemiology study would have been, her opinion that such a study would have spared "numerous patient populations [from] unnecessary risks associated with Viagra"[57] is pure conjecture, and therefore inadmissible.

---

[55] *Id.* at 299–300.

[56] Blume Rep. 19.

[57] *Id*. at 42.

III. DR. BLUME'S OPINION CONCERNING THE MOTIVES, INTENT AND STATE OF MIND OF PFIZER, PRESCRIBING PHYSICIANS AND PATIENTS IS INADMISSIBLE

A. Dr. Blume's Testimony Concerning Pfizer's Motive and Intent Is Inadmissible

Dr. Blume purports to provide opinions regarding Pfizer's motives, intent and state of mind with respect to its response to reports of NAION in association with the use of Viagra. For example, in her report Dr. Blume opines that, "[w]hile Pfizer was aware of these NAION cases in 2000, their response *seemed* to focus on deflecting negative publicity which they knew would result."[58] At deposition, Dr. Blume admitted that her "opinion" that Pfizer "seemed to focus on deflecting negative publicity" was simply her "interpretation" of documents:

> Q. Where in that letter does it say "deflecting negative publicity," Doctor?
>
> A. Oh, it doesn't.
>
> Q. That's your interpretation of the letter, correct?
>
> A. And my paper says, "Their response seemed to focus." I don't have quote marks in that response, nor do I say their response was – did deflect. I said, "It seemed to focus."
>
> Q. Okay. That's your interpretation of the document, correct?
>
> A. Yes. That's – well ***it's my interpretation*** of multiple documents, but yes.[59]

[58] Blume Rep. 13 (emphasis added).

[59] Blume Dep. 204 (emphasis added). *See also id.* at 210–12.

The MDL Court in *Baycol* rejected expert testimony similar to Dr. Blume's. There, Bayer challenged the testimony of an expert toxicologist who opined that the company ignored warnings and inadequately tested the toxicity of Baycol. Concurring with the *Rezulin* MDL Court, the court held such testimony inadmissible:

> The *Rezulin* court held that proposed expert testimony that the pharmaceutical manufacturer interfered with scientific freedom, and suppressed scientific inquiry, pertains to "lay matters which a jury is capable of understanding and deciding without the expert's help. It is no more than arguments and conclusory statements about questions of fact masquerading behind a veneer of technical language." The same is true in this case. *Bayer's motives as to how it proceeded with evaluating Baycol's toxicity, and its reactions to toxicologists's [sic] warnings are issues that can be decided by the jury without expert assistance*.

Baycol, 532 F. Supp. 2d at 1067 (quoting *Rezulin*, 309 F. Supp. 2d at 553) (emphasis added). Similarly, in *Prempro*, the MDL Court excluded the testimony of plaintiffs' regulatory expert that the company put profits ahead of safety:

> Dr. Parisian testified that the marketing plan exemplified when a pharmaceutical company's "marketing takes the first seat as opposed to the science." Dr. Parisian's testimony about the document is devoid of any reference to the FDA or reliance on her expertise as an [sic] regulatory expert – she provided an editorial about pharmaceutical companies putting sales and marketing before science, but gave no testimony from her position as a regulatory expert.

Prempro, 554 F. Supp. 2d at 881–82. *Accord Shaver v. Indep. Stave Co.*, 350 F.3d 716, 723 (8th Cir. 2003) (plaintiff's "speculation" about "motives and actions of his supervisors, without any foundation suggesting that [plaintiff] had personal knowledge of the matters" was inadmissible).

Dr. Blume does not bring any particular expertise to her interpretation of various Pfizer documents. She is not an expert on Pfizer's motives, which would require

her to be a mind reader. Rather than reading minds, she has cobbled together select Pfizer documents from which she speculates about Pfizer's motives, intent and state-of-mind. "The jury [is] capable of drawing its own inferences from the available evidence." *Strong v. E.I. Du Pont de Nemours Co.*, 667 F.2d 682, 686 (8th Cir. 1981).[60] Dr. Blume's "expert" testimony telling the jury what inferences to draw regarding Pfizer's motives and intentions from the documents is therefore inadmissible.

B. Dr. Blume's Testimony Concerning the Thoughts or Habits of Patients and Prescribing Physicians Is Inadmissible

Dr. Blume also offers a number of opinions regarding the thoughts and habits of patients and physicians. For example, she asserts that "men do not always share with their ophthalmologist their use of an erectile dysfunction drug."[61] But other than in her "personal life," Dr. Blume has no particular "expertise in a man's willingness to disclose medication."[62] Thus, because she admittedly is not "qualified as an expert," she may not "testify thereto in the form of an opinion or otherwise." Fed. R. Evid. 702. *Accord Baycol*, 532 F. Supp. 2d at 1047 ("If an expert is not qualified to opine in a particular area . . . such testimony is excluded under Daubert").

---

[60] *Accord Salem v. U.S. Lines Co.*, 370 U.S. 31, 35 (1962) ("[E]xpert testimony not only is unnecessary but indeed may properly be excluded in the discretion of the trial judge 'if all the primary facts can be accurately and intelligibly described to the jury, and if they, as men of common understanding, are as capable of comprehending the primary facts and of drawing correct conclusions from them as are witnesses possessed of special or peculiar training, experience, or observation in respect of the subject under investigation'" (citation omitted)).

[61] Blume Dep. 367.

[62] *Id.* at 378.

In addition, Dr. Blume speculates that the reason not all adverse events are reported is that "health care providers do not associate a patient's complaints or symptoms with a drug-related adverse event," because "[o]ften times the new event is simply considered a component of the patient's medical condition or an unrelated concomitant illness."[63] She also guesses that "many health care providers are simply unaware of the various programs developed to receive this information."[64] Dr. Blume cites no authority for these opinions. Nor can she speak from her experience because she is not a medical doctor[65] and these are not regulatory issues. Thus, such suppositions are not based on any "scientific, technical, or other specialized knowledge, because "the word 'knowledge' connotes more than subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 589, 590. Accordingly, to the extent Dr. Blume speculates regarding the knowledge, thoughts, habits, and considerations of physicians and patients, such testimony is inadmissible. *See Diet Drugs*, 2001 WL 454586, at *18 (plaintiff's regulatory expert not permitted to "surmis[e] as to what physicians would do with different information" because such an opinion was "purely speculative and not based on scientific knowledge").

[63] Blume Rep. 7.

[64] *Id.* at 8.

[65] Blume Dep. 11

IV. DR. BLUME'S OPINIONS REGARDING FOREIGN REGULATORY REQUIREMENTS ARE INADMISSIBLE

Dr. Blume intends to testify that foreign regulatory actions demonstrate that "[t]he collective worldwide experience provided clear notice to Pfizer regarding the need for continued product labeling amplifications relating to NAION and the obligation to initiate/conduct clinical trials."[66] She also intends to testify that the label in the United Kingdom includes "more significant contraindications" regarding NAION than the current U.S. label.[67]

Dr. Blume is unqualified to render these opinions – she admits that she "wouldn't consider [herself] an expert" in "European regulatory requirements,"[68] and there is no evidence that she has any expertise regarding any foreign regulatory requirements. Her testimony on the foreign regulation of Viagra is inadmissible for this reason alone. Fed. R. Evid. 702 (a witness may provide expert testimony only if she is "qualified as an expert by knowledge, skill, experience, training or education").

Moreover, even if Dr. Blume were an expert in foreign regulations (and she is not), her testimony regarding the regulation of Viagra by foreign countries is irrelevant. This is a U.S. product liability litigation involving events that occurred in this country regarding a medication approved by the FDA and used for treatment of patients in the U.S. Courts have repeatedly excluded evidence of actions by foreign regulators in

[66] Blume Rep. 28.

[67] Blume Dep. 285.

[68] *Id.* at 286.

product liability actions that are governed exclusively by American law. For example, in *Jones v. Lederle Laboratories*, where the plaintiff claimed injury from a vaccine, the Second Circuit affirmed the district court's holding that testimony that an alternative vaccine was approved in Japan provided "no acceptable evidence" to support plaintiff's claim that a safer vaccine could be marketed in the United States. 785 F. Supp. 1123, 1126–27 (E.D.N.Y.), *aff'd*, 982 F.2d 63 (2d Cir. 1992). *Accord Hurt v. Coyne Cylinder Co.*, 956 F.2d 1319, 1327 (6th Cir. 1992) (British legal standards excluded in products case); *Deviner v. Electrolux Motor, AB*, 844 F.2d 769, 771 n.2, 773 (11th Cir. 1988) (affirming exclusion of evidence that Swedish standards required chain brakes on chain saws on the ground that "Swedish Standards are not relevant in a U.S. product liability case involving a saw sold in the U.S.").

As the court explained in *Harrison v. Wyeth Labs.*, 510 F. Supp. 1, 4–5 (E.D. Pa. 1980), *aff'd*, 676 F.2d 685 (3d Cir. 1982), a pharmaceutical manufacturer's liability must be judged based solely on its actions *in the country where the alleged injury occurred*, because each country applies its own standards:

> Each government must weigh the merits of permitting the drug's use and the necessity of requiring a warning. Each makes its own determination as to the standards of degree of safety and duty of care. This balancing of the overall benefits to be derived from a products' use with the risk of harm associated with that use is peculiarly suited to a forum of the country in which the product is to be used. Each country has its own legitimate concerns and its own unique needs which must be factored into its process of weighing the drug's merits, and which will tip the balance for it one way or the other. . . .
> . . .
> [F]airness to the defendant mandates that defendant's conduct be judged by the standards of the community affected by its actions.

Thus, it is improper to judge Pfizer's action in this country based on decisions by foreign regulatory agencies.

Furthermore, even if evidence of Viagra-related events in foreign countries had any relevance, which it does not, it should nevertheless be excluded under Fed. R. Evid. 403 on the grounds that it would confuse and mislead the jury. In *Baycol,* for example, the MDL Court rejected a similar attempt to use regulatory events in foreign countries to "demonstrate [that] Defendants had notice of [a drug's] dangerous side effects," because "allowing the admission of evidence of foreign regulatory actions, in a case that is governed by domestic law, would likely cause jury confusion." *Baycol*, 532 F. Supp. 2d at 1054. *Accord Seroquel*, 601 F. Supp. 2d at 1318 (the probative value of foreign regulatory actions "is greatly overmatched by the jury confusion, waste of time, and unfair prejudice that would result if the Court were to allow Plaintiffs to introduce this evidence during their main case").

V. DR. BLUME'S OPINIONS REGARDING REGULATORY ACTIONS WITH RESPECT TO VIAGRA ADVERTISING ARE INADMISSIBLE BECAUSE THE TESTIMONY IS IRRELEVANT

Dr. Blume identifies three instances in which FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") issued letters to Pfizer because three Viagra advertisements did not include certain risk information.[69] These letters are irrelevant.

[69] Blume Rep. 24–25. Copies of the letters are attached as Exs. 86-88 to the Leskin Affirmation.

Two of the three letters that Dr. Blume cites in her report relate to advertising that was disseminated in 2004 and 2008 – long after Mr. Stanley and Mr. Martin developed NAION in 2000 and 2002, respectively.[70] In fact, by 2004, both Mr. Stanley and Mr. Martin had stopped using Viagra.[71] Thus, whether or not such advertising "violated FDA regulations by omitting important safety information"[72] has no bearing on Mr. Martin's or Mr. Stanley's decision to take Viagra.

The third letter, which is dated February 2, 2000, also is irrelevant for two reasons. First, Dr. Blume has no evidence that Mr. Martin, Mr. Stanley or their prescribing physicians saw any of the advertisements referenced in the letter.[73] Without such evidence, there is no "fit" between advertisements referenced in the letter and plaintiffs' claims. *Daubert*, 509 U.S. at 591–92 ("Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility"). Second, the FDA letter has nothing to do with NAION. As is evident from the face of the FDA letter, it does not say (as Dr. Blume contends) that "Pfizer was required to include reference to NAION in its advertisements."[74] In fact, FDA did not

[70] *See* Blume Rep. 25; Leskin Aff. Exs. 87 and 88.

[71] *See* Deposition Transcript of Plaintiff Stanley ("Stanley Dep.") at 126 (Leskin Aff. Ex. 10); Deposition Transcript of Plaintiff Martin ("Martin Dep.") at 195 (Leskin Aff. Ex. 4).

[72] Blume Rep. 25.

[73] Blume Dep. at 303–04. *See also* Martin Dep. 208-09; Stanley Dep. 98.

[74] Blume Dep. 231; Leskin Aff. Ex. 86.

request that Pfizer add information relating to NAION to the Viagra label before 2005.[75] Accordingly, the alleged shortcomings of the advertisements are not relevant to NAION or to these cases, and Dr. Blume's testimony about them should therefore be excluded.

VI. DR. BLUME'S FACTUAL HISTORY OF VIAGRA IS INADMISSIBLE BECAUSE SHE IS SIMPLY PUTTING THE PLAINTIFFS' "SPIN" ON THE FACTS, WITHOUT APPLICATION OF SCIENTIFIC OR REGULATORY EXPERTISE

Twenty pages of Dr. Blume's report are devoted to a "Chronology of Viagra Regulatory Events (United States and Foreign)"[76] and a "Labeling Chronology."[77] In addition to recounting her version of Viagra's regulatory and labeling history as it relates to the issue of NAION, Dr. Blume's narrative discusses events entirely unrelated to the issues in this litigation. None of Dr. Blume's narrative – including that pertaining to NAION – involves the application of her regulatory expertise. Rather, her chronologies are "merely a 'narrative of the case which a juror is equally capable of constructing.'" *Rezulin*, 309 F. Supp. 2d at 551 (expert's "history of Rezulin" was inadmissible). In addition, "[s]uch material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence." *Id.*

In *Prempro*, the Court held that "[h]aving an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony." 554 F. Supp. 2d at 887.

[75] Blume Rep. 22.

[76] *Id.* at 20–28.

[77] *Id.* at 29–40.

Similarly, in *Fisher v. CIBA Specialty Chems. Corp.*, 238 F.R.D. 273, 281 (S.D. Ala. 2006), the court expressed its opinion regarding such factual narratives:

> After studying [plaintiff's regulatory expert's] report, the Court shares defendants' concerns. The document reads like the fact section of a brief, not the report of an expert witness. . . . [The expert's] statements of alleged fact do not appear to benefit from, or to be based to any extent on, [his] status as a regulatory expert.

Such expert testimony "invade[s] areas that require[] no expert testimony," and is therefore "inappropriate 'expert' testimony." *Prempro*, 554 F. Supp. 2d at 887. *Accord*, *Rezulin*, 309 F. Supp. 2d at 553 (expert testimony on foreign regulatory actions excluded; "plaintiffs' experts are not the appropriate vehicles for" the introduction of "foreign regulatory actions;" "[t]he subject of the testimony is lay matter").

Dr. Blume's testimony about the Viagra regulatory and labeling chronology will not "assist the trier of fact," as required by Rule 702. The jury does not need expert testimony to interpret such evidence because it does not relate to "scientific, technical or other specialized knowledge." Fed. R. Evid. 702. An expert should not "'supplant the role of counsel in making argument at trial, and the role of the jury in interpreting the evidence.'" *Prempro*, 554 F. Supp. 2d at 887 n.86 (quoting *Rezulin*, 309 F. Supp. 2d at 551). Dr. Blume's testimony about Viagra's regulatory history is therefore inadmissible.

VII. DR. BLUME FAILED TO MAKE PROPER RULE 26 DISCLOSURES

Finally, Dr. Blume should be precluded from testifying about certain matters because she has failed to disclose the materials she relied upon in forming her opinions. Specifically, she has failed to provide the following items – all of which were requested before, during and after her deposition:

- All time records and billing records relating to any work that Dr. Blume, her staff, and/or any other outside consultant did in connection with the formulation of Dr. Blume's opinions and drafting of Dr. Blume's expert report in this matter;[78]

- A list of search terms that Dr. Blume, her staff, and/or outside consultants used to collect and filter the documents and medical and scientific literature that Dr. Blume used in formulating her opinions and drafting her expert report in this matter;[79]

- An index of documents on a hard drive that Dr. Blume identified in her report as "Pfizer Production Documents" that counsel provided to her;[80]

- Deposition transcripts that Dr. Blume reviewed other than those specifically identified by name in the "List of Reviewed Materials" attached as Exhibit 2 to her report;[81]

- Court filings that Dr. Blume reviewed;[82]

- Supporting materials upon which Dr. Blume relied in asserting at her deposition that direct retinal toxicity is associated with NAION;[83] and

- Supporting materials upon which Dr. Blume relied in testifying that two case reports were not included in the FDA's Adverse Event Reports database.[84]

These materials should have been disclosed in response to a subpoena that was served in advance of Dr. Blume's deposition, which requested, in part, "[a]ll

---

[78] Blume Dep. 35.

[79] *Id.* at 23.

[80] *Id.* at 130–31.

[81] *Id.* at 46.

[82] *Id.* at 51.

[83] *Id.* at 272–73.

[84] *Id.* at 155–56.

documents and materials, published or unpublished, on which you intend to rely as a basis, in whole or in part, for the opinion you intend to express in this litigation."[85] In addition, in the weeks following Dr. Blume's deposition, Pfizer's counsel repeatedly asked plaintiffs' counsel to produce these materials – including a February 18, 2009 letter; a March 6, 2009 e-mail; a March 17, 2009 voice message; and a final demand letter on March 31, 2009 – but plaintiffs' counsel ignored these requests. After two months of unanswered e-mails, letters, and voice-mail messages, Dr. Blume's testimony should be precluded.[86]

"Fed. R. Civ. P. 26(a) and (e) require parties to disclose *all bases of their experts' opinions* and to supplement timely their expert disclosures upon discovery of an omission or as required by court order." *Mitchell v. Ford Motor Co.*, 2009 WL 593897, at *3 (11th Cir. Mar. 9, 2009) (emphasis added) (affirming exclusion of expert testimony where expert failed to offer additional bases for his opinion prior to hearing) (Leskin Aff. Ex. 105). If a party fails to comply with this rule, "the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial." *Id.* (citing Fed. R. Civ. P. 37(c)(1)). *See also Trost v. Trek Bicycle Corp.*, 162 F.3d 1004, 1009 (8th Cir. 1998) (same; affirming exclusion of late expert report); *Transclean Corp. v. Bridgewood Servs., Inc.*, 101 F. Supp. 2d 788, 795–96 (D. Minn. 2000) (same).

[85] *See* Leskin Aff. ¶¶ 36–38 and Leskin Aff. Ex. 51.

[86] *See* Leskin Aff. ¶¶ 39–42 and Leskin Aff. Exs. 52–54.

The materials that have not been disclosed are materials that Dr. Blume relied upon in forming her opinions in this case, including her opinions relating to the relationship between retinal toxicity and NAION and any allegedly missing information from the FDA's adverse event report database. Accordingly, Dr. Blume should be precluded from testifying about such matters.

CONCLUSION

For all of the reasons set forth above, Pfizer's motion to exclude the testimony of Dr. Blume should be granted.

Dated: May 28, 2009

Respectfully Submitted,

S/ Lori B. Leskin
KAYE SCHOLER LLP
Steve Glickstein
Lori B. Leskin
Mark Spatz
425 Park Avenue
New York, NY 10022
212-836-8000

OPPENHEIMER WOLFF & DONNELLY
David P. Graham
3300 Plaza VII
45 S. Seventh Street
Minneapolis, MN 55402
612-607-7000

Counsel for Pfizer Inc.